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Charity Starts in the Womb: New Research Should Allow Healthy Embryos and Federally Funded Stem Cell Research to Coexist

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CHARITY STARTS IN THE WOMB: NEW RESEARCH SHOULD ALLOW HEALTHY EMBRYOS AND FEDERALLY FUNDED STEM CELL RESEARCH TO COEXIST

I. INTRODUCTION

Monitoring stem cell research can be a bit like watching Niagara Falls. Not only do scientific reports pour forth daily, as they do in many other areas of research, but a kind of mist rises up [from] the torrent of news flashes and editorials, making it difficult to separate knowledge from opinion and hope from hype.¹

Many believe that stem cells hold the potential for curing a myriad of debilitating diseases.² According to the President's Council on Bioethics, if stem cells' "healing powers could be harnessed, the medical benefits for humankind would be immense, perhaps ushering in an era of truly regenerative medicine."³ However, stem cell research has been a hotly debated political issue since stem cells were first discovered in 1998.⁴ The ethical issues embedded in stem cell research, which fuel the political debate, stem from *Roe v. Wade*⁵ and grow more complex as the science develops.⁶

1. PRESIDENT'S COUNCIL ON BIOETHICS, MONITORING STEM CELL RESEARCH 15 (pre-publication ed. 2004) [hereinafter MONITORING]. President Bush created the President's Council on Bioethics on November 28, 2001, "to advise the President on bioethical issues related to advances in biomedical science and technology." *Id.* at xvii.

2. See MONITORING, *supra* note 1, at 3. The diseases that stem cell research could affect include "juvenile diabetes, Parkinson's disease, Alzheimer's disease, spinal cord injuries, heart disease, and amyotrophic lateral sclerosis. These terrible diseases shorten life, limit activity (often severely), and cause great suffering both for the afflicted and their families." PRESIDENT'S COUNCIL ON BIOETHICS, HUMAN CLONING AND HUMAN DIGNITY 145 (2002).

3. MONITORING, *supra* note 1, at 3.

4. *Id.* at 26.

5. *Id.* at 23. When the Supreme Court legalized abortion in *Roe v. Wade*, 410 U.S. 113 (1973), one concern was how the aborted fetuses might be used for research purposes. MONITORING, *supra* note 1, at 23. The following year, this concern led to a congressional moratorium on federal funding for "using human fetuses or living embryos." *Id.*

6. See Laurie Zoloth, *Freedoms, Duties, and Limits: The Ethics of Research in Human Stem Cells*, in GOD AND THE EMBRYO: RELIGIOUS VOICES ON STEM CELLS AND CLONING 141, 141-42 (Brent Waters & Ronald Cole-Turner eds., 2003) ("In fact, stem cell research, a technology barely out of the box, is one of the most fervently debated ethical issues of our day, the subject taken up by the United Nations, fourteen international and two American bioethics commissions, the U.S. Senate and House, and two administrations, not to mention nearly every major religious organization and patient care advocacy group.").

There are three main methods of deriving stem cells, each believed by the scientific community to hold potential for medical benefit, and each with unique ethical issues.⁷ The most promising method to date is embryonic stem cell research,⁸ which has heretofore required the embryo's destruction.⁹ Because the embryo's moral status ranges from nonexistent to that of a fully developed human being,¹⁰ the embryo's destruction is the source of most of the debate surrounding embryonic stem cell research.¹¹ This harm to the embryo prevents embryonic stem cell research from receiving federal funding, which is categorically denied for "research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death."¹² President Bush, in his August 9, 2001 speech, did grant federal funding eligibility to embryonic stem cell lines¹³ which had already been established with private funds and qualified under specific guidelines,¹⁴ but these stem cell lines are limited both in number¹⁵ and potential.¹⁶

In August of 2006, Dr. Robert Lanza published a scientific study in *Nature* demonstrating how stem cell lines could be developed for research by removing a single cell from a developing embryo.¹⁷ The research

7. See *infra* notes 29–37 and accompanying text.

8. Ronald B. Miller, *Twenty-Third Annual Health Law Symposium "Contemporary Issues in Children's Health": Ethical Issues in Stem Cell Research, Therapy, and Public Policy*, 26 WHITTIER L. REV. 845, 862 (2005) ("No non-embryonic sources of stem cells . . . have been shown to have anything like the potential to lead to viable treatments for such diseases as juvenile diabetes, Parkinson's and spinal cord injury that stem cells derived from very early embryos do." (quoting Ruth R. Faden & John D. Gearhart, *Facts on Stem Cells*, WASH. POST, Aug. 23, 2004, at A15)).

9. MONITORING, *supra* note 1, at 8.

10. See Miller, *infra* note 120 and accompanying text.

11. Nicholas Wade, *In New Method for Stem Cells, Viable Embryos*, N.Y. TIMES, Aug. 24, 2006, at A1 (noting that the destruction of the embryo is "a principal objection of those who oppose the research").

12. Balanced Budget Downpayment Act, Pub. L. No. 104-99, §128, 110 Stat. 26, 128 (1996); see also MONITORING, *supra* note 1, at 26 n.8 (explaining the Dickey Amendment and its subsequent codifications).

13. See *infra* notes 38–41 and accompanying text.

14. See President George W. Bush, Remarks by President George W. Bush on Stem Cell Research (Aug. 9, 2001), reprinted in PRESIDENT'S COUNCIL ON BIOETHICS, MONITORING STEM CELL RESEARCH app. B (pre-publication ed. 2004).

15. See Joanna K. Sax, *The States "Race" with the Federal Government for Stem Cell Research*, 15 ANNALS HEALTH L. 1, 17 (2006) (noting that seventy-eight stem cell lines are eligible for federal funding and that eleven of those are currently available for research use).

16. Miller, *supra* note 8, at 858 ("A serious problem for stem cell research and therapy limited to use of the cell lines produced prior to the August, 9, 2001 pronouncement by President George W. Bush, is that all were grown on a medium containing mouse feeder cells raising concern of cross-species infection transfer and perhaps immunologic concerns.").

17. Robert Lanza et al., *Human Embryonic Stem Cell Lines Derived from Single Blastomeres*, NATURE, Nov. 23, 2006, 444 at 481–85; see also Karen Kaplan, *Stem Cell Advance Spares Embryos: Bush Officials Say It's Too Soon to Rule on the Process, Which May Ease Ethical Concerns*, CRITICS

establishes a method for embryonic stem cell research that does not result in the embryo's destruction.¹⁸ Dr. Lanza's research thus overcomes the major moral dilemma of previously used techniques¹⁹ and satisfies the requirement of the current federal funding restrictions.²⁰ While private funding for research is available,²¹ public and private motives can differ considerably,²² and "[h]istory has shown that research in this country advances at a faster pace with federal funding."²³ The absence of federal funding impedes the growth of what may prove to be the greatest medical advancement to date.²⁴ Dr. Lanza's new method of embryonic stem cell research should therefore receive federal funding.

In Part II, I will begin by tracing the progress of stem cell research from the discovery of stem cells through Dr. Lanza's innovative study. I will then identify legislative materials—such as the Dickey Amendment—that restrict federal funding for stem cell research, subsequent legislative proposals to alter such restrictions, and the executive policies of Presidents Bill Clinton and George W. Bush concerning federal funding for stem cell research. Third, I will discuss key religious and moral arguments both for and against embryonic stem cell research. In Part III, I will discuss the preexisting moral dilemmas that Dr. Lanza's technique leaves unresolved, new moral dilemmas it creates, and the pros and cons of granting federal funding for stem cell research using Dr. Lanza's technique. In Part IV, I will propose that Dr. Lanza's technique is an ideal middle ground that allows federal funding for embryonic stem cell research by alleviating the

Say There's No Certainty It Doesn't Cause Injury, L.A. TIMES, Aug. 24, 2006, at A1.

18. Lanza, *supra* note 17, at 481.

19. Rick Weiss, *Senators Denounce Scientist's Stem Cell Claims; Confusion Over Harm to Embryos in Study at Issue*, WASH. POST, Sept. 7, 2006, at A4 ("Embryonic stem cells are prized for their medical and research potential, and until Lanza's experiment they had been grown only by methods that necessitated the destruction of an embryo.").

20. See *supra* Part III.A. See also *infra* note 68 (citing current legislative restrictions on federal funding).

21. LAURA BLACK, *THE STEM CELL DEBATE: THE ETHICS AND SCIENCE BEHIND THE RESEARCH* 75 (2006).

22. Suzanne Kadereit & Pamela J. Hines, *An Overview of Stem Cell Research*, 39 NEW ENG. L. REV. 607, 620 (2005) ("Companies have different priorities than public-sector government-supported research, however, which affects the directions the companies choose to research and whether the results will be publicly available.").

23. *Id.*

24. Miller, *supra* note 8, at 857–58 ("Perhaps the biggest ethical issue regarding stem cell research is the potential missed opportunity. If restrictions on research preclude, or even just delay, investigation that might lead to cures, or even just amelioration, of diseases thought to be amenable to the promise of stem cell therapy."); *id.* at 849 ("The potential of stem cell research to result in remarkable therapies is a potential boon to mankind.").

moral concerns raised by federal funding restrictions. Dr. Lanza's technique should therefore receive federal funding.

II. BACKGROUND

A. Stem Cells

The first reported isolation of human embryonic stem cells occurred at the University of Wisconsin in 1998.²⁵ A stem cell is defined by its potential to reproduce indefinitely and by its ability to differentiate itself into different types of cells.²⁶ It is precisely these abilities which make stem cells ideal for medical research purposes,²⁷ and scientists anticipate extraordinary results.²⁸

Stem cells can derive from three sources: embryonic stem cells, embryonic germ cells, and adult stem cells. Embryonic stem cells are typically taken from an embryo five to nine days after it has been fertilized through in vitro fertilization, when the embryo consists of approximately 200 cells.²⁹ The inner cells—which typically develop into the body of the individual—are harvested, resulting in the destruction of the embryo.³⁰ Embryonic germ cells are acquired from five- to nine-week-old aborted fetuses that have been donated for research.³¹ Both embryonic stem cells and embryonic germ cells possess the extraordinary abilities to regenerate and to differentiate into any type of cell in the human body.³² “Because

25. MONITORING, *supra* note 1, at 26.

26. *Id.* at 2 (“Themselves relatively undifferentiated and unspecialized, they can and do give rise to the differentiated and specialized cells of the body (for example, liver cells, kidney cells, brain cells).”).

27. See Kadereit & Hines, *supra* note 22, at 617 (“Embryonic stem cells are so attractive for research because they grow well in culture and retain the property of pluripotency during extended culture growth. Thus, after prolonged culture periods, embryonic stem cells can still produce a wide array of the cells of the body in culture. Embryonic stem cells provide, therefore, an unlimited supply of stem cells and specialized cells for meaningful experiments.”).

28. Miller, *supra* note 8, at 849 (“Stem cell research should yield at least six benefits: (1) Allowing an understanding of disease mechanisms and thus; (2) the design of effective therapy with drugs targeted at basic mechanisms; (3) the repair or replacement of damaged tissues or organs; (4) growing organs in vitro or in vivo to lessen dependence on cadaveric and live donors of organs which are in such short supply that many recipients wait two to five years for a transplant (and many unfortunately die waiting); (5) avoiding immunologic rejection (which at least presently requires somatic cell nuclear transfer (SCNT) from the patient to an egg whose own nucleus was removed; and, (6) it appears that stem cell therapy for spinal cord injury minimizes scarring and releases growth factors which stimulate neural repair.”).

29. MONITORING, *supra* note 1, at 8.

30. *Id.*

31. See *id.* at 9.

32. *Id.*

they are so flexible, it also seems likely that they could be used to produce cell preparations that could then be transplanted . . . to repopulate a part of the body such as the pancreas or spinal cord that has lost function due to disease or injury.”³³ Adult stem cells are derived from “various tissues in children as well as adults.”³⁴ While some believe that adult stem cells could potentially be as flexible as embryonic stem and germ cells,³⁵ adult stem cells are already partially differentiated³⁶ and “biologists are unanimous that even the most potent adult stem cells cannot approach the therapeutic power of embryonic stem cells.”³⁷

Stem cells are only of medical and scientific value if they can be studied, which first requires their isolation and culture.³⁸ Stem cells are placed in a dish along with feeder cells, which provide the nutrients the stem cells need to swiftly multiply.³⁹ The stem cells in the original dish may then be divided and distributed to other dishes to continue culturing.⁴⁰ After the cells have been cultured for six to twelve months, all cells resulting from the original embryo are referred to as one stem cell line.⁴¹

B. Dr. Lanza's Research

About fifty fertility clinics, most in the United States, use a technique known as preimplantation genetic diagnosis (PGD), first used in 1989.⁴² About three days after an embryo's in vitro fertilization⁴³—when the embryo consists of merely eight cells called blastomeres⁴⁴—one of these cells is removed⁴⁵ and tested for genetic markers associated with more

33. *Id.*

34. *Id.* at 10.

35. *Id.*

36. *Id.*

37. CHRISTOPHER THOMAS SCOTT, *STEM CELL NOW: FROM THE EXPERIMENT THAT SHOOK THE WORLD TO THE NEW POLITICS OF LIFE* 89 (2006). *See also* TONEY ALLMAN, *STEM CELLS* 51 (2006) (“Except for the hematopoietic stem cells from bone marrow, adult stem cells are difficult for scientists to use in medical therapies. Adult stem cells are hard to identify and isolate, do not grow easily in the laboratory, and often remain inactive instead of turning on to make new cells.”).

38. *MONITORING*, *supra* note 1, at 3.

39. *BLACK*, *supra* note 21, at 45.

40. *Id.*

41. *Id.*

42. PRESIDENT'S COUNCIL ON BIOETHICS, *REPRODUCTION & RESPONSIBILITY: THE REGULATION OF NEW BIOTECHNOLOGIES* 90 (2004).

43. *Id.* at 91.

44. *Blastomere*, in *THE AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE* (4th ed. 2006), available at <http://dictionary.reference.com/browse/blastomere> (“Any of the cells resulting from the cleavage of a fertilized ovum during early embryonic development.”).

45. *Wade*, *supra* note 11.

than one hundred diseases.⁴⁶ These diseases include Lesch Nyhan syndrome, hemophilia, mental retardation, Down syndrome, Turner syndrome, cystic fibrosis, Tay-Sachs disease, and even Alzheimer disease.⁴⁷ If no markers are identified, the seven-cell embryo is implanted.⁴⁸ While not all clinics practice PGD, estimates suggest that between 1,000 and 2,000 children⁴⁹ have been created through this technique.⁵⁰

Dr. Robert Lanza, medical director of Advanced Medical Technology, was the senior author of a study published in the scientific journal *Nature* in August of 2006.⁵¹ Dr. Lanza demonstrated through his research that the blastomeres removed for PGD could also be used to derive stem cell lines without interfering with the clinic's test.⁵² Using this method, no embryos are destroyed,⁵³ and the ethical considerations are limited to the risk posed to the developing embryo by removing a cell,⁵⁴ or blastomere. While Dr. Lanza's research did result in the destruction of all embryos,⁵⁵ his intent was to demonstrate that a single blastomere could develop into a stem cell line; years of PGD had already established the ability of an embryo to survive the removal of a blastomere.⁵⁶ An apparent goal of the research

46. REPRODUCTION & RESPONSIBILITY, *supra* note 42, at 90.

47. *Id.*

48. Wade, *supra* note 11.

49. REPRODUCTION & RESPONSIBILITY, *supra* note 42, at 90 (quoting Genetics and Public Policy Center, *Preimplantation Genetic Diagnosis: A Discussion of Challenges, Concerns, and Preliminary Policy Options Related to the Genetic Testing of Human Embryos*, Washington, D.C. (2004)).

50. Wade, *supra* note 11 ("Dr. Andrew La Barbera, scientific director of the American Society for Reproductive Medicine, said that more than 2,000 babies had been born in the United States after a preimplantation genetic diagnosis.").

51. Kaplan, *supra* note 17. For the published study, see Lanza, *supra* note 17.

52. "By growing the single blastomere overnight, the resulting cells could be used for both genetic testing and stem cell derivation without affecting the clinical outcome of the procedure." Lanza, *supra* note 17, at 481.

53. Alison Abbott, 'Ethical' Stem-Cell Paper Under Attack: Study in *Nature* Berated for Lack of Clarity, *NATURE*, Sept. 6, 2006, <http://www.nature.com/news/2006/060904/full/443012a.html> (explaining that Dr. Lanza carried out his research to demonstrate the viability of such method—which allows an embryo to continue developing after the removal of a single cell for testing—but noting that he did not actually employ this method in his research).

54. *Id.* ("Norio Nakatsuji of Kyoto University, who derived Japan's only human embryonic stem-cell lines, points out that the process poses a small risk to the baby.").

55. Rick Weiss, *Critic Alleges Deceit in Study on Stem Cells: Report's Basic Facts Are Unchallenged*, *WASH. POST*, Aug. 26, 2006, at A2 ("In the experiments, the scientists took as many cells as they could from each embryo, destroying them in the process, to make the most of the embryos donated for their study."); see also Abbott, *supra* note 53 ("Lanza says he never intended to say more than that he had proved a principle, and that . . . the established procedure of pre-implantation genetic diagnosis . . . has already shown that embryos from which a blastomere has been removed survive. 'We knew that, so we took multiple cells from each embryo so as not to be wasteful,' he says.").

56. Weiss, *supra* note 55.

was, in fact, to create a technique which would allow federal funding for embryonic stem cell research.⁵⁷

C. Legislation

The current debate over federal funding for stem cell research stretches back to 1973,⁵⁸ twenty-five years before embryonic stem cells were first isolated.⁵⁹ After the Supreme Court handed down its decision in *Roe v. Wade*,⁶⁰ Congress began to consider how science might use, or possibly abuse, aborted fetuses.⁶¹ Endorsing the policy of the Department of Health, Education and Welfare,⁶² Congress passed a law in 1974 temporarily denying any “federal funding for clinical research using ‘a living human fetus, before or after the induced abortion of such fetus, unless such research is done for the purpose of assuring the survival of such fetus.’”⁶³ The blanket ban was lifted the following year, when the regulation of federal funding for human embryo research was returned to the Department of Health, Education and Welfare.⁶⁴ The Department never approved funding,⁶⁵ and the choice was taken out of its hands in 1996 when Representative Jay Dickey proposed a ban on federal funding for research that could harm human embryos or that created human embryos specifically for research purposes.⁶⁶ The “Dickey Amendment,” “attached to the Health and Human Services appropriations bill each year

57. Abbott, *supra* note 53 (“[Lanza] hopes the methodology will provide a source of stem cells compatible with US law, which prohibits public funding of research into new human embryonic cell lines derived at the expense of embryos.”).

58. MONITORING, *supra* note 1, at 23.

59. *Id.* at 26.

60. 410 U.S. 113 (1973). In *Roe v. Wade*, the Supreme Court held that anti-abortion laws violate a woman’s right to privacy under the Fourteenth Amendment.

61. MONITORING, *supra* note 1, at 23.

62. *Id.* (After *Roe v. Wade*, the Department of Health, Education and Welfare “initiated a moratorium on any potential DHEW sponsorship or funding of research using human fetuses or living embryos.”). The Department of Health, Education and Welfare was the forerunner of today’s Department of Health and Human Services. *Id.*

63. *Id.*

64. In 1975, the task of providing advice on federal funding standards for human embryo research fell to the newly created Ethics Advisory Board created within the Department of Health, Education and Welfare. While the Board determined in 1979 that research involving human embryos less than fourteen days old which had been donated by married couples was ethical, the Board did not offer an opinion as to what, if any, federal funding such research should receive. *See id.* at 23–24.

65. The charter for the Ethics Advisory Board, through which funding requests for embryonic research had to go, lapsed in 1980, in effect creating another moratorium. Congress nulled the Board’s involvement in 1993, passing such funding decisions to the National Institutes of Health (NIH). MONITORING, *supra* note 1, at 24. The NIH failed to approve any funding before the passage of the Dickey Amendment. *Id.* at 25.

66. *Id.* at 25.

since 1996,”⁶⁷ specifically forbids federal funding for “research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death”⁶⁸ Embryos for which federal funding is forbidden include those “derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.”⁶⁹ However, the amendment in no way affects private funding of such research.⁷⁰ The Dickey Amendment “effectively prohibits the use of federal funds to support any research that destroys human embryos or puts them at serious risk of destruction,”⁷¹ but, according to a generally accepted and presidentially endorsed⁷² interpretation proposed by the Department of Health and Human Services,⁷³ the federal government might nevertheless fund embryonic stem cell research after the embryo has been destroyed.⁷⁴ Still, some argue

67. *Id.*

68. Balanced Budget Downpayment Act, Pub. L. No. 104-99, §128, 110 Stat. 26, 128 (1996). The most modern version of the amendment in its entirety reads:

(a) None of the funds made available in this Act may be used for—

(1) the creation of a human embryo or embryos for research purposes; or

(2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.204(b) and section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)).

(b) For purposes of this section, the term “human embryo or embryos” includes any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

Department of Health and Human Services Appropriations Act 2006, Pub. L. No. 109-149, §509, 119 Stat. 2833, 2280 (2005). 45 C.F.R. § 46.204, to which the Dickey Amendment refers, reads in pertinent parts as follows:

Pregnant women or fetuses may be involved in research if all of the following conditions are met:

... (b) The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means.

45 C.F.R. § 46.204 (2007). “(b) Risk standard for fetuses intended to be aborted and fetuses intended to be carried to term to be the same.” 42 U.S.C. § 289g (2006).

69. MONITORING, *supra* note 1, at 26 (quoting Balanced Budget Downpayment Act, I, Pub. L. No. 104-99, § 128, 110 Stat. 26, 128 (1996)).

70. *Id.*

71. *Id.*

72. *Id.* at 27 (noting that both President Clinton and President Bush have used this interpretation in forming related policies).

73. *Id.* (citing Memorandum from Harriet S. Rabb, Gen. Counsel of the Dept. of Health and Human Services, to Harold Varmus, Dir. of the Nat’l Institutes of Health (Jan. 15, 1999) (on file with the National Archives)).

74. By funding research that was made possible by the prior destruction of an embryo, as

that this interpretation violates the “spirit of the law.”⁷⁵ Embryonic stem cells were not isolated until two years after the initial passage of the Dickey Amendment.⁷⁶

In May of 2005, four years after President George W. Bush announced a policy that declared future stem cell lines ineligible for federal funding,⁷⁷ the House of Representatives passed a bill to allow federal funding for research on certain types of stem cell lines.⁷⁸ Under the Stem Cell Research Enhancement Act of 2005,⁷⁹ stem cell lines derived from leftover and unneeded embryos from in vitro fertilization clinics would have been eligible for federal funding,⁸⁰ “regardless of the date on which the stem cells were derived.”⁸¹ The bill was stalled in the Senate until late June of 2006,⁸² but the measure passed in July 2006 by a vote of sixty-three to thirty-seven.⁸³ As promised,⁸⁴ President Bush vetoed the bill.⁸⁵ The two-thirds majority needed to override the veto was fifty-one votes shy in the House, with a vote of 235–193.⁸⁶ Many other bills relating to the federal funding policy for embryonic stem cell research have been proposed and others are still pending, but none have passed both houses of Congress.⁸⁷

opposed to funding research that itself destroys the embryo, the Department argued that federal funds would not be going to research “in which” human embryos were injured. *Id.*

75. *Id.* at 27 n.10 (“This case was made, for instance, in a letter authored by Rep. Jay Dickey and signed by seventy other members of Congress to DHHS Secretary Donna Shalala, February 11, 1999.”).

76. *Id.* at 25–26.

77. Bush, *supra* note 14, at 184. President Bush stated that federal funding would be limited to those stem cell lines which had already been derived by the date of his speech: August 9, 2001. *Id.*

78. *Senate Revives Bill to Finance Stem Cell Research*, N.Y. TIMES, June 29, 2006, available at 2006 WL 11316582.

79. Stem Cell Research Enhancement Act of 2005, H.R. 810, 109th Cong. (2005).

80. *Id.*

81. *Id.* Because the bill would have made federal funding available to stem cell lines without reference to the date of stem cell derivation, the bill would have gone against President Bush’s policy limiting federal funding to those lines derived before August 9, 2001. *See infra* note 92 and accompanying text.

82. *Senate Revives Bill to Finance Stem Cell Research*, *supra* note 78. Nancy Reagan is credited with helping the bill pass in the House and for pushing the bill through its stall in the Senate. In 2004, Former President Ronald Reagan succumbed to Alzheimer’s disease, the effects of which could one day be relieved or even alleviated through stem cell research. *Id.*

83. Carl Hulse, *Senate Approves a Stem Cell Bill; Veto Is Expected*, N.Y. TIMES, July 19, 2006, at A1.

84. Peter Baker, *President Vows Veto On Stem Cell Research: Bipartisan Measure Seeks to Ease Curbs*, WASH. POST, May 21, 2005, at A6.

85. Letter from George W. Bush, President of the U.S., to the House of Representatives (July 19, 2006), available at <http://www.whitehouse.gov/news/releases/2006/07/20060719-5.html>.

86. Sheryl Gay Stolberg, *First Bush Veto Maintains Limits on Stem Cell Use*, N.Y. TIMES, July 20, 2006, at A1.

87. *See, e.g.*, Stem Cell Research Expansion Act, S. 362, 110th Cong. (2007) (proposing to allow

D. Effect of the Executive

In contrast to the Bush administration, President Clinton endorsed embryonic stem cell funding under certain conditions. Under Clinton's policy, the embryos were limited to those leftover from fertility procedures, and stem cells must have previously been harvested from these embryos with private funding.⁸⁸ Donors must have consented to the embryo's use for research, without enticement, but the embryo must not have been specifically created for that purpose.⁸⁹ These guidelines were completed as Clinton's second presidential term was coming to an end. The guidelines were therefore never implemented, and corresponding funding was never awarded.⁹⁰

President Bush stayed President Clinton's policy when he took office in 2001.⁹¹ President Bush's policy, which he announced in a speech on August 29, 2001,⁹² had the objective of utilizing stem cells that had already been harvested without encouraging further embryo destruction.⁹³ According to President Bush, "extracting the stem cell destroys the embryo, and thus destroys its potential for life."⁹⁴ Therefore, federal funding would only be granted to stem cell lines in which stem cells had already been removed, to the point of preventing the embryo's further development, before 9:00 p.m. Eastern Time on August 9, 2001.⁹⁵

federal funding for stem cell lines derived before January 23, 2006, such that federal dollars would not fund the destruction of an embryo); Alternative Pluripotent Stem Cell Therapies Enhancement Act, S. 2754, 109th Cong. (as passed by Senate, July 13, 2006) (proposing that federal funds be directed toward the "isolation, derivation, production, or testing" of non-embryonic sources of pluripotent stem cells); Stem Cell Replenishment Act of 2005, H.R. 162, 109th Cong. (2005) (proposing that stem cell lines be eligible for federal funding regardless of their dates of derivation, but in all other ways remaining subject to the current NIH guidelines).

88. National Institutes of Health Guidelines for Research Using Human Pluripotent Stem Cells, 65 Fed. Reg. 51975 (Aug. 25, 2000), *reprinted in* PRESIDENT'S COUNCIL ON BIOETHICS, MONITORING STEM CELL RESEARCH app. D, at 191 (pre-publication ed. 2004) ("Studies utilizing pluripotent stem cells derived from human embryos may be conducted using NIH funds only if the cells were derived (without Federal funds) from human embryos that were created for the purposes of fertility treatment and were in excess of the clinical need of the individuals seeking such treatment.").

89. *Id.* at 191-92.

90. MONITORING, *supra* note 1, at 28.

91. *Id.*

92. Bush, *supra* note 14, at 181.

93. MONITORING, *supra* note 1, at 28 and 34.

94. Bush, *supra* note 14, at 182.

95. Office of the Dir. of the Nat'l Institutes of Health, Notice of Criteria for Federal Funding of Research on Existing Human Embryonic Stem Cells and Establishment of NIH Human Embryonic Stem Cell Registry (Nov. 7, 2001), *reprinted in* PRESIDENT'S COUNCIL ON BIOETHICS, MONITORING STEM CELL RESEARCH app. C, at 187 (pre-publication ed. 2004).

President Bush estimated that over sixty existing stem cell lines would be eligible for this federal funding.⁹⁶

President Bush recognized the potential in the existing stem cell lines: they were “genetically diverse,” able to “regenerate themselves indefinitely,” and would enable “us to explore the promise and potential of stem cell research without crossing a fundamental moral line.”⁹⁷ However, limiting federal funding to these stem cell lines has severe drawbacks. First, “the limited number of cell lines that the Bush administration approved for federally funded research is, at best, adequate only for basic research to determine the most promising avenues for further exploration.”⁹⁸ According to the director for the National Institutes of Health, seventy-eight stem cell lines are eligible for federal funding.⁹⁹ However, “eligibility is not the same thing as availability.”¹⁰⁰ The seventy-eight eligible lines will not all become available for use,¹⁰¹ eighteen of them already having become permanently unavailable.¹⁰² As of September 2003,¹⁰³ only twelve lines were available to the scientific community,¹⁰⁴

96. Bush, *supra* note 14, at 184 (“As a result of private research, more than 60 genetically diverse stem cell lines already exist . . . I have concluded that we should allow federal funds to be used for research on these existing stem cell lines, where the life and death decision has already been made.”).

97. *Id.*

98. Richard M. Doerflinger, *The Ethics and Policy of Embryonic Stem Cell Research: A Catholic Perspective*, in *STEM CELL RESEARCH: NEW FRONTIERS IN SCIENCE AND ETHICS* 143, 150 (Nancy E. Snow ed., 2003).

99. Sax, *supra* note 15, at 17 (citing *Stem Cell Research, Hearing Before Senate Appropriations Subcommittee on Labor: Health and Human Services, and Education*, 108th Cong. (2003) (statement of Elias A. Zerhouni), available at <http://olpa.od.nih.gov/hearings/108/session1/testimonies/stemcell.asp>). As of January 25, 2007, the number of eligible stem cell lines was still seventy-eight. Nat’l Institutes of Health, Information on Eligibility Criteria for Federal Funding of Research on Human Embryonic Stem Cells, <http://stemcells.nih.gov/research/registry/eligibilitycriteria> (last visited Jan. 25, 2007).

100. MONITORING, *supra* note 1, at 42.

101. *See id.* at 43 (“The process of establishing a human embryonic stem cell line, turning the originally extracted cells into stable cultured populations suitable for distribution to researchers, involves an often lengthy process of growth, characterization, quality control and assurance, development, and distribution. In addition, the process of making lines available to federally funded researchers involves negotiating a contractual agreement (a ‘materials transfer agreement’) with the companies or institutions owning the cell lines, establishing guidelines for payment, intellectual property rights over resulting techniques or treatments, and other essential legal assurances between the provider and the recipient.”). An additional hurdle to availability is that these lines can change over time, and “[c]hromosomal alterations have already been observed in a few of the approved cell lines.” Kadereit & Hines, *supra* note 22, at 620.

102. Nat’l Institutes of Health, Information on Eligibility Criteria for Federal Funding of Research on Human Embryonic Stem Cells, *supra* note 99. Reasons for the stem cell lines’ unavailability include “the cells failed to expand into undifferentiated cell cultures,” “cell line no longer eligible for federal funding,” and the cell line’s withdrawal by its donor. *Id.*

103. MONITORING, *supra* note 1, at 42.

and by January 2007, this number had risen to just twenty-one stem cell lines worldwide that are both eligible for federal funding and available for use.¹⁰⁵ The number of available lines is important because many more will be needed for clinical applications “in order to provide an immunological match for as many patients as possible.”¹⁰⁶ Second, all seventy-eight of the eligible lines were grown using mouse feeder cells, “raising concern of cross-species infection transfer and perhaps immunologic concerns,”¹⁰⁷ and further limiting the viability of the lines currently eligible for federal funding.

In July of 2006, President Bush vetoed a bill that would have annulled his federal funding policy for embryonic stem cell research.¹⁰⁸ It was the first veto of his presidency.¹⁰⁹ The Stem Cell Research Enhancement Act of 2005 would have allowed federal funding for stem cell lines derived from embryos that were created for in vitro fertilization but were no longer needed and would otherwise have been destroyed.¹¹⁰

President Bush has also not endorsed Dr. Lanza’s new technique. A White House spokeswoman stated, “Any use of human embryos for research purposes raises serious ethical questions. This technique does not resolve those concerns.”¹¹¹ She later stated that President Bush would hold his opinion for further analysis of Dr. Lanza’s research.¹¹²

104. *Id.* at 43 (citing NIH Stem Cell Registry website at <http://stemcells.nih.gov>).

105. Nat’l Institutes of Health, Information on Eligibility Criteria for Federal Funding of Research on Human Embryonic Stem Cells, *supra* note 95.

106. Kadereit & Hines, *supra* note 22, at 621. Obtaining an immunological match between the stem cells and the recipient is important because the recipient’s body will otherwise identify the stem cells as “foreign” and attack and kill the cells. Studies show that embryonic stem cells could be capable of immune rejection just as whole organ transplants are currently. Organ transplant recipients must take immunosuppressive drugs, which carry significant side effects, for the rest of their lives in order to keep their bodies from rejecting the donor organs. Researchers hope to avoid the same fate for stem cell recipients by eliminating the immune rejection problem. MONITORING, *supra* note 1, at 131–32.

107. Miller, *supra* note 8, at 858. *See also* Kadereit & Hines, *supra* note 22, at 620 (warning that use of the government-funded stem cell lines, which were cultured with mouse feeder cells, entails the risk of introducing murine viruses in humans—a potential cross-species contamination as was recently seen with SARS and avian flu).

108. Stolberg, *supra* note 86; *see also supra* note 85.

109. Stolberg, *supra* note 86.

110. *Id.*; *see also supra* notes 79–86 and accompanying text.

111. Wade, *supra* note 11 (quoting White House spokeswoman Emily Lawrimore).

112. Editorial, *A Way Out?: Scientists Might Now Be Able to Harvest Stem Cells Without Harming Embryos*, WASH. POST, Aug. 28, 2006, at A14.

E. Religious Arguments and Moral Concerns

[I]n his new book on the embryo research debate, Professor Ronald Green—formerly vice-chair for ethics of the Human Embryo Research Panel at the National Institutes of Health (NIH)—writes that the Catholic bishops conference of the United States has been “the most active and effective center of opposition to all facets of human embryo research” and now to embryonic stem cell research.¹¹³

Indeed, much of the opposition to and even some of the support for embryonic stem cell research derives from religious beliefs.¹¹⁴

“The stem cell itself is not the turf to be won; rather, it is the moral status of the embryo from which the stem cell is derived.”¹¹⁵ The embryo’s moral status is central to the religious debate over embryonic stem cell research. At some point an embryo changes from a cluster of cells to a human being, but at what precise point in its development this change occurs is unclear.¹¹⁶ An embryo refers less to a specific being than it does to a “certain *stage of development*,”¹¹⁷—a stage that precedes that of fetus,¹¹⁸ which precedes birth.¹¹⁹

Although all agree the blastocyst is human and is living, some hold that this mass of thirty cells that is barely visible and only the size of the head of a pin, has no human form, has no nervous system, is

113. Doerflinger, *supra* note 98, at 143 (quoting RONALD GREEN, *THE HUMAN EMBRYO RESEARCH DEBATES: BIOETHICS IN THE VORTEX OF CONTROVERSY* 158 (2001)).

114. BLACK, *supra* note 21, at 89–92 (explaining that the Catholic and Jewish perspectives are perhaps the best represented in the media because their religious doctrines more clearly support one side of the debate where other religious doctrines leave the issue open to individual interpretation; explaining why the Catholic position opposes embryonic stem cell research and the Jewish position supports it). See also Ted Peters, *The Stem Cell Controversy*, in *THE STEM CELL CONTROVERSY: DEBATING THE ISSUES* 231, 232 (Michael Ruse & Christopher A. Pynes eds., 2d ed. 2006) (“[T]his is not merely a matter of science and public policy; it is a religious issue.”).

115. Ted Peters & Gaymon Bennett, *A Plea for Beneficence: Reframing the Embryo Debate*, in *GOD AND THE EMBRYO*, *supra* note 6, at 111, 112.

116. Ronald Cole-Turner, *Principles and Politics: Beyond the Impasse over the Embryo*, in *GOD AND THE EMBRYO*, *supra* note 6, at 88, 89–92 (discussing the difficulty in determining the moral status of a developing embryo and noting the difference between biological development and the development of the embryo’s moral status).

117. MONITORING, *supra* note 1, at 12.

118. *Id.* at 147 (presenting multiple “embryo” definitions, each with the embryo ceasing to exist when it becomes known as a fetus); see also BLACK, *supra* note 19, at 41 (noting that most scientists agree that the term *human embryo* “refers to a fertilized egg cell during the first two months of its development,” after which it is known as a fetus).

119. MONITORING, *supra* note 1, at 148.

not a person, has no soul, and thus need not be accorded the protection due to persons or ensouled beings. Others, however, believe that from the very moment of conception because the zygote-morula-blastocyst has the potential to become a child and later an adult, it has full moral status and must not be harmed or destroyed.¹²⁰

To kill a human being without justification is murder, but to destroy human tissue is innocent.¹²¹ The embryo's moral status seems to range between that of human tissue and human being,¹²² leading some to err on the side of caution. For others, the potential benefit of this research to an existing human being takes precedence over the harm to a potential human being.¹²³

With the moral complexity of the embryo as a foundation, another argument is that researchers should invest their time—and the government its money—in stem cells from adult tissue instead of those from an embryo.¹²⁴ In addition to the elimination of moral concerns,¹²⁵ adult stem

120. Miller, *supra* note 8, at 852. The Catholic Church is among those who believe that an embryo, as well as a fetus, holds the moral status of a human being. Elisabeth Rosenthal, *Excommunication Is Sought for Stem Cell Researchers*, N.Y. TIMES, July 1, 2006, at A3. However, a Jewish scholar, considering a clinically created embryo a potential human life, notes that “a possible thing is not the same as the thing itself, and we treat each being relative to our duties at that time. We can agree, for example, that with utter certainty each of us will become a corpse, yet we do not treat one another as corpses.” Zoloth, *supra* note 6, at 143. See also ALLMAN, *supra* note 37, at 25 (noting that many scientists do not consider an embryo to be the beginning of a life until it has implanted itself in the womb since that is the first time the embryo begins to differentiate into an organism, and as many as three of every four embryos die without implanting themselves).

121. See Andrew Sullivan, *Only Human*, THE NEW REPUBLIC, July 30, 2001, at 8 (comparing the moral status of embryos to that of fingernail clippings). President Bush has said that he does not consider the destruction of an embryo to be murder. *Bush Spokesman Retracts Stem Cell Comment*, N.Y. TIMES, July 25, 2006, at A16. If embryo destruction were considered murder, privately funded research would be prohibited and criminal sanctions would be in place. MONITORING, *supra* note 1, at 26 (“At the federal level, research that involves the destruction of embryos is neither prohibited nor supported and encouraged.”). Therefore, since not prohibited, killing an embryo is not illegal under United States federal law.

122. See HUMAN CLONING AND HUMAN DIGNITY, *supra* note 2, at 152. In its report, the President's Council on Bioethics asks, “Is destroying an embryo or cloned embryo at the blastocyst stage morally the same as killing a child? Is it the same as clipping a fingernail? Is it more like one of these acts than the other? Is it like neither?” *Id.*

123. See SCOTT, *supra* note 37, at 130.

124. See, e.g., Wade, *supra* note 11 (noting that Dr. Leon Kass, former chairman of the President's Council on Bioethics, finds adult stem cells preferable to Dr. Lanza's technique, which Dr. Kass called “inefficient.”).

125. MONITORING, *supra* note 1, at 10–11 (“Research involving adult stem cells raises few difficult ethical concerns, beyond the usual need to secure free and fully informed consent from donors and recipients, a favorable benefit-to-risk ratio for all participants in attempts at therapy, and protection of privacy. Adult stem cells are less controversial than embryonic ones, as we have noted, because the former can be collected without lasting harm to the donor.”); EVE HEROLD, STEM CELL

cell research is useful because “[i]mmune rejection could be avoided if one could use the patient’s own tissues.”¹²⁶ However, adult stem cells do not show the promise that embryonic stem cells do.¹²⁷ Recent discoveries suggest that adult stem cells might be as elastic as non-adult stem cells,¹²⁸ “[b]ut there are unanswered questions about the ease of culture and long-term viability of such cells, and the likelihood of success with cellular models of disease derived from adult stem cells remains unknown.”¹²⁹ Moreover, while using a patient’s adult stem cells might help with immune rejection, patients who could benefit from stem cell therapy often cannot provide enough healthy tissue to be of use.¹³⁰

Other objections have been made which apply specifically to Dr. Lanza’s research. For example, some have asserted that the use of even one blastomere could mean the destruction of potential life.¹³¹ However, the President’s Council on Bioethics warns that “[p]ersons interested in the debate should note at the outset that [embryonic stem cells and embryonic germ cells] are not themselves embryos; they are not whole organisms, nor can they be made (directly) to become whole

WARS: INSIDE STORIES FROM THE FRONTLINES 62 (2006) (noting that “there is no objection from any quarter to scientists pursuing research on adult stem cells”).

126. Kadereit & Hines, *supra* note 22, at 615.

127. *Id.* at 617 (“Embryonic stem cells are so attractive for research because they grow well in culture and retain the property of pluripotency during extended culture growth. Thus, after prolonged culture periods, embryonic stem cells can still produce a wide array of the cells of the body in culture. Embryonic stem cells provide, therefore, an unlimited supply of stem cells and specialized cells for meaningful experiments. Moreover, once the specifics have been worked out, these cells can give rise to clinically relevant cell numbers and could thus be used with greater ease in therapies than adult stem cells.”).

128. MONITORING, *supra* note 1, at 10. Non-adult stem cells include both embryonic and germ stem cells. *See generally supra* notes 31–39 and accompanying text.

129. HUMAN CLONING AND HUMAN DIGNITY, *supra* note 2, at 148.

130. Kadereit & Hines, *supra* note 22, at 615 (“[S]ome victims of severe burns do not have enough skin left to generate replacement tissue. Or, for patients with advanced degenerative diseases, most of the relevant tissue has already been destroyed. In addition, current observations suggest that adult stem cells age, and that the regenerative capacity of these cells decreases with increasing age. Thus, older patients may not be able to provide the cells necessary for their treatments.”).

131. Editorial, *Stem Cells Without Embryo Loss*, N.Y. TIMES, Aug. 26, 2006, at A14 (“[Lanza’s] approach won’t satisfy those who believe that even a single cell removed from an early embryo may have the potential to produce life.”); Rick Weiss, *Stem Cells Created with No Harm to Human Embryos; But Concerns Are Raised About the Technique*, WASH. POST, Aug. 24, 2006, at A03 (noting that some, including “Richard Doerflinger of the U.S. Conference of Catholic Bishops,” are concerned that one cell from an embryo could develop into another embryo); Wade, *supra* note 11 (quoting a spokesperson for Senator Sam Brownback as stating that developing a blastomere into a stem cell line is the equivalent of “creating a twin and then killing that twin.”).

organisms.”¹³² Scientists have been unsuccessful in coaxing “a single cell taken from an eight-cell embryo” into becoming an embryo itself.¹³³

A final relevant argument concerns the health of the children who develop from these seven-cell embryos following pre-implantation genetic diagnosis (PGD).¹³⁴ Estimates for the number of children born using the technique have exceeded 2000.¹³⁵ Though more time and study is needed to ensure the method’s safety, babies born using PGD do not appear to be at greater risk than in vitro babies born without the procedure.¹³⁶

III. ANALYSIS

President Bush’s 2001 policy identifies the problem in this area by what it aims to rectify: the clash of moral sentiment and desire for medical progress.¹³⁷ It is a problem of weighing the harm to a potential life versus the potential benefit to an existing life. To benefit the scientific community through federal funding, Dr. Lanza’s method must comply with both the Dickey Amendment and President Bush’s 2001 policy. To resolve the embedded problem, Dr. Lanza’s method must overcome moral objections. Whether the method can overcome these obstacles may depend on the current state of medical evidence.

132. MONITORING, *supra* note 1, at 4.

133. Weiss, *supra* note 131 (“Experiments have shown that some mammals can develop from a single cell taken from a four-cell embryo. But several scientists yesterday said no mammal has ever been grown from a single cell taken from an eight-cell embryo—a more advanced stage of development in which each cell has already become somewhat specialized.”). *But see* ALLMAN, *supra* note 37, at 24–26 (explaining that through the eight-cell stage, embryonic stem cells remain totipotent—“capable of giving rise to every cell needed to grow an embryo, a fetus, and then a person”—but by the next division to sixteen cells, totipotency yields to pluripotency, meaning the stem cells could still form any cells of the body but “cannot form all the cells necessary to create a new life, such as those that give rise to the placenta”).

134. REPRODUCTION & RESPONSIBILITY, *supra* note 42, at 94 (positing the possibility of danger that removing a blastomere from a young embryo could pose to the resulting human being and noting the lack of information available).

135. Wade, *supra* note 11 (“Dr. Andrew La Barbera, scientific director of the American Society for Reproductive Medicine, said that more than 2,000 babies had been born in the United States after a preimplantation genetic diagnosis.”).

136. *See infra* note 160 and accompanying text. *See also* HEROLD, *supra* note 125, at 34 (“At such an early stage of existence, the process [of removing one cell for PGD] does not destroy the embryo; if implanted, it could still develop into a normal baby.”).

137. Bush, *supra* note 14, at 184 (asserting that his policy “allows us to explore the promise and potential of stem cell research without crossing a fundamental moral line”).

A. Does Dr. Lanza's Method Conform to Current Legislation and Policy?

President Bush's 2001 policy was an attempt to reconcile the conflict of morality versus science.¹³⁸ President Bush wanted to keep to the "spirit" of the Dickey Amendment while federally supporting stem cell research.¹³⁹ Bush's policy actually relied on the same interpretation of the Dickey Amendment that the Clinton Administration did, finding that the federal government could technically fund stem cell research which relied on an embryo's destruction so long as the destruction occurred before federal funding came into play.¹⁴⁰ This is a valid interpretation of the law as written,¹⁴¹ but President Bush only honored the amendment's spirit to the extent that his policy discouraged *further* embryo destruction¹⁴² (or in the Dickey Amendment, also "risk of injury").¹⁴³ If the Dickey Amendment's spirit is the protection of embryos, then President Bush's policy could be said to violate that spirit to the extent that it rewards past embryo destruction.

A method for embryonic stem cell research that would satisfy the stated aims of Bush's 2001 policy, then, is one in which an embryo is neither put in harm's way nor outright destroyed. Such a method would not only meet the aims and requirements of Bush's policy,¹⁴⁴ but because the method would never involve an embryo's destruction at any stage of research, it would satisfy the "spirit"—and indeed precise requirements—of the Dickey Amendment without creative interpretation. Though Dr. Lanza's research in fact resulted in the destruction of all sixteen embryos, the technique which his study aimed to prove does not destroy the

138. *Id.* at 183 ("At its core, this issue forces us to confront fundamental questions about the beginnings of life and the ends of science. It lies at a difficult moral intersection, juxtaposing the need to protect life in all its phases with the prospect of saving and improving life in all its stages.").

139. MONITORING, *supra* note 1, at 28.

140. *Id.* at 27. All seventy-eight stem cell lines eligible for federal funding resulted from the destruction of embryos. Press Release, The White House, Fact Sheet: Embryonic Stem Cell Research (Aug. 9, 2001), available at <http://www.whitehouse.gov/news/releases/2001/08/20010809-1.html>. Therefore, President Bush's policy would have been precluded by the Dickey Amendment without Bush's reliance on this interpretation.

141. See MONITORING, *supra* note 1, at 27.

142. Bush, *supra* note 14, at 184.

143. President Bush did not mention "risk of injury" along with "destruction" since the only known method of procuring embryonic stem cells at that time was via an embryo's destruction. See Bush, *supra* note 14, at 182 ("Research on embryonic stem cells raises profound ethical questions, because extracting the stem cell destroys the embryo, and thus destroys its potential for life."). Since the Dickey Amendment also mentions "risk of injury," I will assume that President Bush's aim also encompasses "risk of injury."

144. See *supra* note 95 and accompanying text.

embryo.¹⁴⁵ The question for Dr. Lanza's method is therefore whether removing a blastomere presents potential harm to the eight-cell embryo.

B. "Risk of Injury"¹⁴⁶ to the Embryo and Resolution of Moral Issues

The removal of blastomeres for diagnostic testing is a technique fertility clinics have employed for about ten years.¹⁴⁷ Research shows that the tiny embryo recovers from the loss of a cell, and by all appearances, develops into a healthy baby.¹⁴⁸ Yet unknown is what effects the early removal of a blastomere might have on long-term human development.¹⁴⁹ As of this writing, the oldest child created using PGD would be merely ten years old—hardly sufficient time for the scientific community to form conclusions as to PGD's safety in the long term. Nevertheless, all evidence thus far points to the safety of PGD not only for the embryo¹⁵⁰ but also for the resulting human being.¹⁵¹

The Dickey Amendment and President Bush's stem cell policy each refer to the embryo. Scientifically, the term *embryo* indicates "a certain stage of development."¹⁵² The Dickey Amendment, however, more specifically and more broadly defines an embryo as "any organism, not protected as a human subject . . . , that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells."¹⁵³ An obvious legal question, then, is whether potential developmental harm to the resulting adult is legally relevant, since that adult would then be "protected as a human subject" and outside the parameters of the Dickey Amendment.¹⁵⁴ Nevertheless, such harm would challenge the "spirit" of the amendment,¹⁵⁵ with healthy development of the experimental embryo part of its goal.¹⁵⁶

145. Weiss, *supra* note 55.

146. MONITORING, *supra* note 1, at 25–26 (quoting section 128 of Balanced Budget Downpayment Act, I, Pub. L. No. 104-99, 110 Stat. 26 (1996)).

147. Wade, *supra* note 11.

148. *Id.*

149. REPRODUCTION & RESPONSIBILITY, *supra* note 42, at 94.

150. SCOTT, *supra* note 37, at 120 (explaining that an "embryo recovers with a quick round of cell division" after having one of its eight cells removed for PGD).

151. See *supra* note 136 and accompanying text.

152. MONITORING, *supra* note 1, at 12; see also notes 118–19 and accompanying text.

153. Department of Health and Human Services Appropriations Act 2006, Pub. L. No. 109-149, § 509, 119 Stat. 2833, 2280 (2005).

154. *Id.*

155. MONITORING, *supra* note 1, at 27.

156. As a mere rider to the annual appropriations bill, little legislative history exists to elucidate Congress's intent for the Dickey Amendment. See *supra* note 67 and accompanying text. The "spirit" of the amendment seems to be the protection of nascent human life from government-funded

Another possible harm concerns not the remaining seven-cell embryo but the removed blastomere. If that single blastomere could develop into another embryo, then its use for the creation of a stem cell line could be seen as the destruction, or perhaps prevention, of an embryo. This would bring the moral dilemma full circle in that the experimental use of the blastomere might be viewed as the scientific harm of potential life. Again, the legal relevance of this concern is questionable since the blastomere, even if capable of becoming an embryo, is not technically an embryo at this point but merely a single-celled representative.¹⁵⁷ The Dickey Amendment regulates the scientific use of embryos, not potential embryos.¹⁵⁸ For now, however, the inquiry is moot. Scientists have been unsuccessful in coaxing a blastomere extracted from an eight-cell embryo into becoming an embryo.¹⁵⁹

C. State of Medical Evidence and Efficiency

Dr. Lanza's method requires more medical knowledge. To know whether or not PGD poses a developmental harm to the human beings created using this technique, time and study are needed.¹⁶⁰ Additionally, since Dr. Lanza's is the first experiment utilizing the PGD technique to culture stem cell lines, the scientific community requires replication of the study in order to verify that blastomeres removed through PGD can develop into stem cell lines.¹⁶¹

More specific problems with Dr. Lanza's study have been suggested. First, "the new method, if confined to blastomeres derived from PGD, would not provide a highly desired type of cell, those derived from patients with a specific disease."¹⁶² However, disease-specific stem cell

destruction and harm. See MONITORING, *supra* note 1, at 28. It therefore seems logical that this spirit would also entail the protection of actual human life from harm resulting from government-funded testing at the embryonic stage (e.g., the spirit would not condone embryonic experimentation to produce a living Cyclops).

157. THE AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE, *supra* note 44.

158. See Department of Health and Human Services Appropriations Act 2006, Pub. L. No. 109-149, § 509, 119 Stat. 2833, 2280 (2005).

159. See *supra* note 133.

160. Wade, *supra* note 11 ("Dr. Andrew La Barbera, scientific director of the American Society for Reproductive Medicine, said that more than 2,000 babies had been born in the United States after a preimplantation genetic diagnosis. There is no sign yet that they have any greater risk of disease than other in vitro fertilization babies, but the society needs more data to be sure, Dr. La Barbera said.").

161. *A Way Out?: Scientists Might Now Be Able to Harvest Stem Cells Without Harming Embryos*, *supra* note 112.

162. Wade, *supra* note 11 (referencing Dr. Irving Weissman, a stem cell expert at Stanford University).

testing is already being done with little to no ethical controversy¹⁶³ and without the help of Dr. Lanza's research.¹⁶⁴ Disease-specific cells are taken from patients who have the disease that scientists wish to study, so disease-specific cells are non-embryonic, or adult, stem cells.¹⁶⁵ These cells are taken from the tissue of living humans, and the only real ethical issues concern the donor's safety and consent.¹⁶⁶

Another problem is inefficiency, which no one has debated and which even Dr. Lanza admits.¹⁶⁷ Only two of the ninety-one blastomeres cultured developed into stem cell lines.¹⁶⁸ However, the government has made clear that the barriers to government funding for embryonic stem cell research exist because of moral, not efficiency, concerns.¹⁶⁹

Finally, Dr. Lanza cultured his stem cells using animal ingredients, which could entail potential problems for human use¹⁷⁰ similar to those of mouse feeder cells in the current federally funded stem cell lines.¹⁷¹ Dr. Lanza is currently "developing non-animal nutrients" in order to solve this problem.¹⁷²

Dr. Lanza's technique honors the "spirit" of the Dickey Amendment more so than President Bush's stem cell policy does.¹⁷³ All available medical evidence suggests that the PGD process poses no risk of injury to the remaining seven-celled embryo,¹⁷⁴ and that the single cell removed for PGD could not itself become an embryo.¹⁷⁵ The few problems that Dr.

163. See MONITORING, *supra* note 1, at 10.

164. Kadereit & Hines, *supra* note 22, at 621 ("For the most rapid progress towards human therapies, however, both types of stem cells, adult and embryonic, have to be investigated in more detail and in conjunction with one another. The strongest research in adult stem cells will be in concert with research in embryonic stem cells, and vice versa. Both types of stem cells have to be seen as one research field, consisting of two complementary entities.").

165. See MONITORING, *supra* note 1, at 10.

166. *Id.*

167. Rick Weiss, *New Method Makes Embryo-Safe Stem Cells*, WASH. POST, Aug. 24, 2006, at A3 ("The process is inefficient, Lanza acknowledged—and would probably be even more so if researchers were limited to taking just one cell per embryo.").

168. *Id.*

169. The efficiency of research is something for scientists to worry about. The government's only efficiency concern should be economic—whether or not its money is being spent efficiently. However, this economic concern in no way affects any moral considerations and should have no bearing on whether or not Dr. Lanza's method receives federal funding. The United States government has created a precedent in directing millions of dollars toward less-promising adult stem cell research, choosing ethics over efficient spending.

170. Weiss, *supra* note 167.

171. See *supra* note 107 and accompanying text.

172. Weiss, *supra* note 167.

173. See *supra* notes 138–45 and accompanying text.

174. See *supra* notes 147–51 and accompanying text.

175. See *supra* note 133.

Lanza's research now faces are to be expected with a new scientific technique, and public funding will help those problems to be resolved more rapidly.¹⁷⁶

IV. PROPOSAL

Dr. Lanza's technique should be monetarily endorsed by the federal government. President Bush's 2001 policy sought to monetarily propel medical scientific advancement while honoring the "spirit" of the Dickey Amendment.¹⁷⁷ Basically, Bush hoped to reconcile moral and scientific aims. Dr. Lanza seems to have achieved Bush's goal better than Bush himself. Federal funding for Dr. Lanza's technique would not encourage the destruction of or harm to embryos. Unlike Bush's 2001 policy, though, funding Dr. Lanza's technique would not require the past destruction of embryos, either. The "spirit" of the Dickey Amendment is to discourage future embryonic harm,¹⁷⁸ but since the amendment never included a provision grandfathering past scientific research thenceforth forbidden, the spirit could also be said to include a refusal to reward prior unethical behavior. In this sense, the funding of Dr. Lanza's research would go further than President Bush's 2001 policy. Dr. Lanza's technique not only encompasses the spirit of the Dickey Amendment but also conforms to the precise letter of the amendment without invoking creative interpretation.¹⁷⁹ Dr. Lanza's technique for deriving embryonic stem cell lines should therefore be eligible for federal funding.

Adult stem cells do not show the same promise that embryonic stem cells do in their potential for medical advancement.¹⁸⁰ Nevertheless, adult stem cell research is not subject to any restrictions in order to be eligible for federal funding.¹⁸¹ The National Institutes of Health consistently provides significantly higher levels of funding to adult stem cell research than it does to human embryonic stem cell research.¹⁸² Admittedly, the

176. See *supra* note 23 and accompanying text.

177. MONITORING, *supra* note 1, at 28.

178. *Id.* at 27.

179. *Id.* ("If embryos were first destroyed by researchers supported by private funding, then subsequent research employing the derived embryonic stem cells, now propagated in tissue culture, might be considered eligible for federal funding.").

180. See Kadereit & Hines, *supra* note 22, at 617. See also SCOTT, *supra* note 37 and accompanying text.

181. HEROLD, *supra* note 125, at 62.

182. SCOTT, *supra* note 37, at 171 ("In 2003, the NIH provided just \$27 million for [human embryonic stem cell] research—only on the 20 or so approved lines—and 8 times that amount for research on adult stem cells."); HEROLD, *supra* note 125, at 62 ("In 2005, the same year that the NIH invested over \$607 million in stem cell research overall, research using *human embryonic* stem cells

only technique previously available for the derivation of embryonic stem cells¹⁸³ was plagued by moral questions and debate, but Dr. Lanza's technique of growing embryonic stem cell lines while sparing the embryos has largely alleviated those concerns. The United States government should not favor a less promising technology over a technology with largely moribund moral issues.

The former federal concern involved weighing the potential benefit of embryonic stem cell research to existing life against the destruction or harm to potential life. Using Dr. Lanza's technique, the embryo's potential for development will not be extinguished, so the scale should tip in favor of the benefit to existing life. Dr. Lanza's technique should acquire federal funding now since every second counts for those who can benefit.¹⁸⁴

V. CONCLUSION

The controversy over Dr. Lanza's research technique involves a significant moral component, but ultimately whether or not the research receives funding is a matter of law and policy, not morality. Sometimes these concepts attempt to coexist and sometimes not, but in a subject area in which one demographic can have so many different ideas of applied morality,¹⁸⁵ morality and the law can never be in perfect harmony.

In the case of stem cell research, law and policy were created specifically in the name of morality.¹⁸⁶ Until now, the progress of medical science has confined embryonic stem cell research to obligatory embryo destruction,¹⁸⁷ and as a result, policy has confined federally funded researchers to an inadequate number of sub-quality stem cell lines.¹⁸⁸ Dr. Lanza's technique preserves, by all known accounts, a healthy

received only \$39 million. In other words, the NIH spent about fourteen times as much on animal and adult stem cell research as it did on human embryonic stem cell research.”).

183. See *supra* notes 29–30 and accompanying text.

184. Miller, *supra* note 8, at 857–58.

185. Bush, *supra* note 14, at 181 (“The issue is debated within the church, with people of different faiths, even many of the same faith coming to different conclusions.”).

186. MONITORING, *supra* note 1, at 28 (“This is the ethical-legal logic of [President Bush’s 2001] stem cell funding policy: it seeks those benefits of embryonic stem cell research that might be attainable without encouraging or contributing to any future destruction of human embryos.”).

187. David P. Hamilton & Antonio Regalado, *New Questions Emerge Over Stem-Cell Research Claims*, WALL ST. J., Sept. 5, 2006, at A15.

188. Doerflinger, *supra* note 98, at 150 (“For, the limited number of cell lines that the Bush administration approved for federally funded research is, at best, adequate only for basic research to determine the most promising avenues for further exploration. The currently eligible cell lines are not only of insufficient volume for treatments, but they also have inadequate genetic diversity to treat most of the patients who may want cell implants; and they are grown in cultures of mouse feeder cells, which could make them inappropriate for human transplantation.”).

embryo¹⁸⁹—all but eliminating moral concerns—and offers the possibility of myriad quality embryonic stem cell lines. The sooner the federal government grants funding for this technique, the sooner this possibility can be realized.¹⁹⁰

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189. *A Way Out?: Scientists Might Now Be Able to Harvest Stem Cells Without Harming Embryos*, *supra* note 112 (“The rest of the embryo can grow into a normal human child, according to all available scientific evidence.”).

190. Bush, *supra* note 14, at 182 (“Scientists further believe that rapid progress in [embryonic stem cell] research will come only with federal funds.”). This would, in fact, be the first time that quality embryonic stem cell lines were eligible for federal funding, since all of the currently eligible lines are contaminated with mouse feeder cells. *See supra* notes 16 and 107 and accompanying text. The problems with Dr. Lanza’s technique, such as efficiency, could also be solved more quickly with federal funding. *See supra* note 23 and accompanying text.

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